

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 413**

**[CMS-1531-F]**

**RIN 0938-AO35**

**Medicare Program; Revision of the Deadline for Submission of Emergency  
Graduate Medical Education Affiliation Agreements**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule responds to comments on and revises the deadline for submission of the 2006 emergency Medicare graduate medical education (GME) affiliation agreements. The deadlines to submit the emergency Medicare GME affiliation agreements for the 2005 through 2006 and 2006 through 2007 academic years are changed from on or before June 30, 2006 and July 1, 2006, respectively, to on or before October 9, 2006.

**DATES:** These regulations are effective on June 30, 2006.

**FOR FURTHER INFORMATION CONTACT:**

Elizabeth Truong, (410) 786-6005.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

**A. Legislative and Regulatory History**

The stated purpose of section 1135 of the Social Security Act (the Act) is to enable the Secretary to ensure, to the maximum extent feasible, in any emergency area

and during an emergency period, that sufficient health care items and services are available to meet the needs of enrollees in Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). Section 1135 of the Act authorizes the Secretary, to the extent necessary to accomplish the statutory purpose, to temporarily waive or modify the application of certain types of statutory and regulatory provisions (such as conditions of participation or other certification requirements, program participation or similar requirements, or pre-approval requirements) with respect to health care items and services furnished by health care provider(s) in an emergency area during an emergency period.

The Secretary's authority under section 1135 of the Act arises in the event there is an "emergency area" and continues during an "emergency period" as those terms are defined in the statute. Under section 1135(g) of the Act, an emergency area is a geographic area in which there exists an emergency or disaster that is declared by the President according to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act, and a public health emergency declared by the Secretary according to section 319 of the Public Health Service Act. (Section 319 of the Public Health Service Act authorizes the Secretary to declare a public health emergency and take the appropriate action to respond to the emergency, consistent with existing authorities.) Throughout the remainder of this discussion, we will refer to such emergency areas and emergency periods as "section 1135" emergency areas and emergency periods.

When Hurricane Katrina occurred on August 29, 2005, disrupting health care operations and medical residency training programs at teaching hospitals in New Orleans

and the surrounding area, the conditions were met for an emergency area and emergency period under section 1135(g) of the Act. Under section 1135 of the Act, the Secretary was then authorized to waive a number of provisions to ensure that sufficient services would be available in the section 1135 emergency area to meet the needs of Medicare, Medicaid, and SCHIP patients. Shortly after Hurricane Katrina occurred, we were informed by hospitals in New Orleans that the training programs at many teaching hospitals in the city were closed or partially closed as a result of the disaster and that the displaced residents were being transferred to training programs at host hospitals in other parts of the country. For purposes of discussion in this rule, a host hospital is a hospital that trains residents displaced from a training program in a section 1135 emergency area. A home hospital is a hospital that meets all of the following: (1) is located in a section 1135 emergency area (2) had its inpatient bed occupancy decreased by 20 percent or more due to the disaster so that it is unable to train the number of residents it originally intended to train in that academic year, and (3) needs to send the displaced residents to train at a host hospital.

In the April 12, 2006 **Federal Register** (71 FR 18654), we published an interim final rule with comment period to modify the Graduate Medical Education (GME) regulations as they apply to Medicare GME affiliations to provide for greater flexibility during times of disaster. Specifically, the interim final rule implemented the emergency Medicare GME affiliated group provisions to address issues that may be faced by certain teaching hospitals in the event that residents who would otherwise have trained at a hospital in an emergency area (as that term is defined in section 1135(g) of the Social Security Act (the Act)) are relocated to alternate training sites. To provide home

hospitals with more flexibility to train displaced residents at various sites, and to allow host hospitals to count displaced residents for IME and direct GME, home hospitals may enter into emergency Medicare GME affiliation agreements effective retroactive to the date of the first day of the section 1135 emergency period.

#### B. Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a)(3) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule finalizes one provision set forth in the April 12, 2006 interim final rule with comment period. In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

## **II. Provisions of the Final Rule**

In this final rule we are responding to comments regarding the deadline for submission of emergency Medicare GME affiliation agreements and finalizing the provision from the April 12, 2006 interim final rule with comment period, specified at §413.79(f)(6)(ii), regarding this deadline. We will issue a separate **Federal Register**

document to respond to comments received and finalize the other provisions of the April 12, 2006 interim final rule with comment period.

In the April 12 interim final rule with comment period, we specified that for the year during which the section 1135 emergency was declared, each hospital participating in the emergency affiliation must submit a copy of the emergency Medicare GME affiliation agreement, as specified under §413.79(f)(6), to CMS and the CMS FI servicing each hospital by the later of 180 days after the section 1135 emergency period begins or by June 30 of the relevant training year. The interim final rule also specified that emergency Medicare GME affiliation agreements for the subsequent 2 academic years must be submitted by the later of 180 days after the section 1135 emergency period begins or by July 1 of each of the years. Furthermore, amendments to the emergency Medicare GME affiliation agreement to adjust the distribution of the number of full-time equivalent (FTE) residents in the original emergency Medicare GME affiliation among the hospitals that are part of the emergency Medicare GME affiliated group can be made through June 30 of the academic year for which they are effective.

We received a number of written comments to the interim final rule provision regarding the timely submission of the emergency Medicare GME affiliation agreements. A summary of the comments received on this provision and our responses are as follows:

Comment: Commenters expressed concern that the year 2006 deadlines for submission of the emergency Medicare GME affiliation agreements (that is, June 30, 2006 and July 1, 2006 for the first and second effective years, respectively) are too restrictive and impose a hardship on hospitals that are coping with the destructive effects of Hurricane Katrina and Rita, which have made even basic daily operations

difficult. A commenter noted that the interim final rule with comment period was posted for public display on April 7, 2006, thereby giving hospitals only 84 days to negotiate and finalize agreements that often involve multiple parties and complex calculations to sort out the various cap transfers before the June 30, 2006 deadline.

Response: The June 30 and July 1 dates were selected at the time the interim final rule with comment period was published based on-- (1) the current requirements for signing Medicare GME affiliation agreements; (2) the beginning of the academic year for residency programs, and (3) the belief that hospitals training residents were likely to want signed affiliation agreements in effect prior to the beginning of the residency training year. We had drafted the interim final rule with comment period to apply, not only to hospitals affected by the 2005 hurricanes, but to any similarly catastrophic event affecting hospitals in the future. Accordingly, the provision was drafted to allow hospitals until the later of 180 days after the section 1135 emergency period begins or June 30 to submit the emergency affiliation agreement for the academic year during the which the emergency occurs, and until the later of 180 days after the section 1135 emergency period begins or July 1 of the relevant training year to submit the emergency agreement for the subsequent 2 academic years. We now recognize that the hospitals affected by Hurricanes Katrina and Rita had only 79 days from April 12, 2006, the date that the interim final rule with comment period appeared in the **Federal Register**, to finalize their written agreements. This is a far shorter period than 180 days after the section 1135 emergency period began, which is the period allow by our regulations in the event of future emergencies. We recognize and appreciate that it may not be administratively possible for all home and host hospitals to submit to the appropriate FIs

and CMS all emergency Medicare GME affiliation agreements resulting from Hurricanes Katrina and Rita, due on or before June 30, 2006 (for the 2005 through 2006 academic year) and July 1, 2006 (for the 2006 through 2007 academic year) because of the limited timeframe in which the affected hospitals had to negotiate and finalize these agreements.

Therefore, in response to the many requests for an extension on the year 2006 deadlines, in this final rule we are revising §413.79(f)(6)(ii) to extend the deadline for emergency Medicare GME affiliation agreements that would otherwise be required to be submitted by June 30, 2006 or July 1, 2006 to October 9, 2006, which is 180 days after the April 12, 2006 interim final rule with comment period.

### **III. Waiver of the Delay in the Effective Date**

The Administrative Procedure Act (APA) normally requires a 30-day delay in the effective date of a final rule. This delay may be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary or contrary to the public interest, and incorporates a statement of the finding and the reasons for it in the rule issued. The Secretary is subject to a similar requirement pursuant to section 1871(e)(1)(B) of the Act.

We find that good cause exists to waive the 30-day delay in effective date because it would be contrary to the public interest to delay the effective date of this final rule. We believe that there is urgent need for the regulation changes provided in this final rule to ensure that hospitals affected by Hurricanes Katrina and Rita do not face dramatic disruptions in their Medicare GME funding, with possible dire effects on their GME programs and financial stability. The existing regulations do not provide adequate time for hospitals to submit their emergency Medicare GME affiliation agreements for the 2005 through 2006 and the 2006 through 2007 academic years.

#### **IV. Collection of Information Requirements**

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

#### **V. Regulatory Impact Statement**

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This final rule does not reach the economic threshold and thus is not considered a major rule. In addition, we expect that there will not be an additional cost to the Medicare program due to our extension of the deadline to submit 2006 emergency Medicare GME affiliation agreements to October 9, 2006.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues

of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

### **List of Subjects in 42 CFR Part 413**

Health facilities, Kidney disease, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV part 413 as set forth below:

**PART 413-- PRINCIPLES OF REASONABLE COST REIMBURSEMENT;  
PAYMENT FOR END-STAGE RENAL DISEASE SERVICES:  
PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED  
NURSING FACILITIES**

1. The authority citation for part 413 continues to read as follows:

**Authority:** Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861 (v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d),

1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww)  
Sec 124 of Pub. L. 106–113, 113 Stat. 1515.

**Subpart F--Specific Categories of Costs**

2. Section 413.79 is amended by revising paragraph (f)(6)(ii) to read as follows:

**§413.79 Direct GME payments: Determination of the weighted number of FTE residents.**

\* \* \* \* \*

(f) \* \* \*

(6) \* \* \*

(ii) Deadline for submission of the emergency Medicare GME affiliation agreement. (A) Except for emergency Medicare GME affiliation agreements that meet the requirements of paragraph (f)(6)(ii)(B) of this section, each participating hospital must submit an emergency Medicare GME affiliation agreement to CMS and submit a copy to its CMS fiscal intermediary by --

(1) First year. The later of 180 days after the section 1135 emergency period begins or by June 30 of the academic year in which the section 1135 emergency was declared; or

(2) Two subsequent academic years. The later of 180 days after the section 1135 emergency period begins, or by July 1 of each academic year for the 2 subsequent academic years.

(B) For emergency Medicare GME affiliation agreements that would otherwise be required to be submitted by June 30, 2006 or July 1, 2006, each participating hospital

must submit an emergency Medicare GME affiliation agreement to CMS and submit a copy to its CMS fiscal intermediary on or before October 9, 2006.

\* \* \* \* \*

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

**Dated:** \_\_\_\_\_

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**Mark B. McClellan,**

Administrator,

Centers for Medicare & Medicaid Services.

**Approved:** \_\_\_\_\_

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**Michael O. Leavitt,**

Secretary.

**BILLING CODE 4120-01-P**